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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,506	04/12/2004	Carl G. Hellerqvist	22100-0202 (49530-299673)	3571

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/823,506	**Applicant(s)** HELLERQVIST ET AL.	
	Examiner Ruixiang Li	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *82,83,85-89,97-100 and 102-105*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: the new limitation added to claim 97 would require further consideration. Because there is no limitation to the isolated antibody or a fragment thereof, a new rejection would be applicable.

Continuation of 5. Applicant's reply has overcome the following rejection(s): the rejection of claim 97 under 35 U.S.C. 112, second paragraph set forth in the previous office action would have been overcome if the amendment were entered.

Continuation of 11. does NOT place the application in condition for allowance because: the rejections of claims 82, 83, 85-89, 97-100, 102-105 under 35 U.S.C. 112, first paragraph for scope of enablement and written description are maintained. Whle the amendment to the claims have removed the issues related to "a polypeptide fragment thereof", the issues related to GBS toxin receptor variants or homologues still remain.

(i). The rejection of claims 82, 83, 85-89, 97-100, 102-105 under 35 U.S.C. 112, first paragraph for scope of enablement

While the amendment to the claims have removed the issues related to "a polypeptide fragment thereof", the issues related to GBS toxin receptor variants or homologues still remain. Moreover, with respect to claim 97, the new limitation, "wherein the reagent for detection of the GBS toxin receptor is an isolated antibody or a fragment thereof", which does not require that the isolated antibody or a fragment thereof possess any structural and functional limitations. Thus, one of skilled in the art would not know how to make and use such a broad genus of antibodies.

With respect to amended claim 97, Applicants argue that claim 97 and its dependent claims specifiy that the reagent for the detection of the GBS toxin receptor is an isolated antibody or a fragment thereof. This is not persuasive because the claims do not have any structural and functional limitations for the recited antibodies and fragments thereof.

(ii). The rejection of claims 82, 83, 85-89, 97-100, 102-105 under 35 U.S.C. 112, first paragraph for written description

Applicants argue that application provides adequate written description for a genus of GBS toxin receptors with 86% identity to SEQ ID NO: 8. Applicants submit that the parent application of the present application was found to provide adequate written description for a genus of GBS toxin receptor having 86% identity. Citing prior art, Applicants argue that the application as filed, in combination with knowledge available to one of ordinary skill in the art in the field of the present application, describes a genus of GBS toxin receptors with 86% identity to SEQ ID NO: 8 in such a way as to reasonably convey to one skilled in the art in the field of the present application that inventors, at the time the application was filed, had possession of the claimed invention. This is not persuasive because (i).each application is examined on its own merit and (ii). the disclosure fails to provide a representative number of GBS toxin receptors that has at least about 86% identity to SEQ ID NO: 8 and fails to describe the conserved structure for the binding domain of GBS toxin receptor.

Applicants argue that application provides sufficient written description for antibodies or fragments thereof that bind GBS toxin receptor with 86% sequence identity to SEQ ID NO: 8. This is not persuasive because applicants were not in possession of the genus of GBS toxin receptors with 86% identity to SEQ ID NO: 8 for the above reasons and thus were not in possession of the genus of antibodies and fragments thereof that bind to GBS toxin receptor with 86% sequence identity to SEQ ID NO: 8.

With respect to claim 105, Applicants argue that support for claim 105 is found throughout the specification, as filed. This is not persuasive because there is no support for the isolated composition that is isolated from a human.

Ruixiang Li

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PRIMARY EXAMINER